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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040219

Application Number: 09/556,701
Filing Date: April 24, 2000
Appellant(s): NISHINO ET AL.

James K. Kelly
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11-18-2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Upon consideration, the 102 rejection of claims 1-3, 7-8 and 12 has been withdrawn.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-3, 7-8, 12, 16 and 17 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

WO 97/20555	***LIFE RESSUSCITATION TECHNOLOGIES, INC.***	***6-1997***
4,687,763	***WURTMAN***	***8-1987***
5,137,871	***WEI***	***8-1992***

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-3, 7-8, 12 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/20555.

WO discloses a method of treatment or prevention of ischemic brain injury by administering melatonin (note the abstract, page 8, lines 10-30, page 9, lines 22-34, page 11, lines 14-16, Examples and claims). Since ischemia is the causative factor of brain edema, it would have been obvious to one of ordinary skill in the art that a composition, which is able to prevent ischemia, would be preventing the edema also. Although WO does not specifically state the composition is a food composition, it

teaches the administration of the composition orally using additives and therefore, addition to food for oral consumption is deemed to be within the skill of the art.

Appellant's arguments based mostly on Dr. Torii's declaration have been fully considered, but are not found to be persuasive. First of all, the examiner would like to point out that the declaration is not based on any experimental evidence. Dr. Torii argues that brain edema is a condition in which excess fluid accumulates in brain tissue which results in the swelling of the brain tissue and that nowhere it is stated in WO 555 that the subjects described therein were suffering from the symptoms of brain edema. Dr. Torii also argues that while it is true that ischemia is a cause of brain edema, the fact that a subject has an ischemic brain injury does not mean that the subject must also have brain edema. Dr. Torii further argues that there is no direct relationship between the clinical symptoms of ischemic patients and brain edema. These arguments are not found to be persuasive. First of all, the last statement by Dr. Torii appears to contradict appellant's statements and the examples in instant application. For example, in the last paragraph on page 2 of the specification appellant states, "once a subject was (?) suffered from brain edema irrespective of the cause of deterioration of cellular permeability, the brain edema itself leads to a secondary disorder such as a disturbance of a cerebral blood flow, ischemia, hypoxia, cerebral hernia and the like due to the increase in intracranial pressure". WO teaches 'ischemic injury and, one cannot rule out edema as the cause of the ischemia in WO. Therefore, WO, which is suggestive of treatment of ischemic injury treatment by melatonin, is also suggestive of treatment of edema. Further support can be seen from Wei (5,137,871) cited by the examiner who

states on col. 3, line 15 et seq., "It is an object of the present invention to decrease the leakage of blood components into brain tissue, a condition called vasogenic edema of the brain, that is produced by various adverse medical conditions, such as brain ischemia, ----" and on col. 4, line 16 et seq., "when an injury to the brain occurs, such as brain ischemia, or infarction, vasogenic edema occurs and the increased amounts of water compress and distort brain tissue architecture and impede the delivery of oxygen to brain cells. These statements establish a strong correlation between ischemia and edema. It should be noted in this context that WO repeatedly uses the term, 'ischemic injury' and not just 'ischemia' and on page 12 line 21 through page 13 line 12, WO suggest the combination of melatonin with mannitol to ***reverse cerebral swelling.*** "Finally, a careful evaluation of the examples instant specification indicates that appellant's studies involve only ischemia and edema per se and appellant draws conclusions based on those studies.

With regard to claim 3 :- claim 3 recites 'an encapsulating matrix or liposome'. Claims are given the broadest reasonable interpretation and WO teaches the administration of melatonin in the form of emulsions containing hydrophobic phase which is emulsified in an aqueous medium on page 10, line 17 through page 11, line 13 (oil in water emulsions wherein water is the continuous phase). Melatonin is in essence is encapsulated in Oil (matrix) which in turn is surrounded by water which also serves as a matrix.

Claims 8, 12, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/20555, further in view of Wurtman (4,687,763).

The teachings of WO have been discussed above. Although WO teaches the administration of melatonin orally, it does not specifically teach that the oral composition be a food composition. It is deemed obvious to one of ordinary skill in the art to administer food composition containing melatonin in the oral mode of administration taught by WO with a reasonable expectation of success, since the reference of Wurtman shows that melatonin is routinely administered as a component of food including a drink, a beverage, a wafer or candy (note the abstract and col. 2, lines 19-59).

Appellant's arguments have been fully considered, but are not found to be persuasive. Appellant's arguments regarding WO have already been addressed above. Appellant's only argument is that US 763 fails to describe or suggest administering melatonin to treat brain edema. This argument is not found to be persuasive since US 763 is combined for its teachings of the knowledge in the art of administration of melatonin in food compositions and therefore, one of ordinary skill in the art would be motivated to administer melatonin as a component of food preparations.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK
February 19, 2004

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